

## **REMARKS/ARGUMENTS**

### **A. Status of the Claims**

Claims 1, 6, 7, 8, and 13 have been amended without prejudice.

New claims 15 to 17 have been added.

Support for the amended and new claims can be found throughout the specification and in the original claims. In particular, support for the amendments to claim 1 can be found, e.g., on page 1, first paragraph in the subsection OBJECT OF THE INVENTION. Support for the amendments to claim 7 can be found, e.g., on page 9, second and third paragraph. Support for new claims 15 to 17 can be found, e.g., on page 9, last paragraph.

Applicants respectfully submit that no new matter has been added by virtue of these amendments.

### **B. Claim Rejections- 35 U.S.C. § 112**

Claim 6 was rejected under 35 U.S.C. § 112, second paragraph, for containing the term “essential oil.”

Claim 6 has been amended without prejudice to delete the objected term.

With regard to new claims 15 and 17 which recite the term “essential oil,” Applicants submit that “essential oil” is commonly used in the art. *See, e.g., U.S. Patent No. 4,910,205, column 1, lines 60, to column 2, lines 4 (“[E]ssential oils are volatile oil that impart the characteristic odors to plants ...[and include, e.g.] eucalyptus, spearmint, cedarwood, wintergreen, peppermint and rosemary oils ...”).* Accordingly, Applicants submit that the meaning of the term is discernable to one skilled in the art, and therefore claims 15 and 17

definite. *See e.g., MPEP section 2173.02* (“a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible”).

Withdrawal of the rejection is respectfully requested.

**C. Claim Rejections- 35 U.S.C. § 102**

Claims 1-8 and 13-14 were rejected under 35 U.S.C. § 102(b) over US Patent No. 5,900,230 to Cutler (“the Cutler patent”).

The rejection is respectfully traversed.

The Cutler patent describes dental products in which the active is a mixture of xylitol and polaxamers. The Cutler patent states that the dental products described therein “**must** contain no less than 10 weight percent of xylitol.” *See column 5, lines 37-38*. The Cutler patent further states that the dental product is “**free** of irritating flavors and essential oils ... [and] are also **free** of harsh antimicrobials.” *See Id., lines 40-47*.

**Claims 1, 2-6 and 14**

Independent claim 1 is directed in part to an oral hygiene product comprising “an amount of the active in the oral hygiene product is from 0.1% to 5%.”

The Cutler patent does not teach a dental product in which an amount of the active in the oral hygiene product is from 0.1% to 5%,” at the very least because the dental products of the Cutler patent “**must** contain no less than 10 weight percent of xylitol.” *See column 5, lines 37-38*. In other words, the amount of the active in the Cutler patent would necessarily be 10 weight percent or more of the dental product.

The Cutler patent thus does not teach each and every element of claim 1, and therefore cannot anticipate claim 1.

Claims 2-6 and 14 depend from claim 1 and include all the features of claim 1. Therefore, claims 2-6 and 14 are also novel over the Cutler patent.

With further regard to claim 14, Applicants submit that the Cutler patent does not teach an oral hygiene product “in the form of an animal feed.” Applicants further submit that the term “in the form of an animal feed” is not merely “an intended use of the composition.” In fact, it defines the product of claim 1. Accordingly, this term should be taken into account in determining patentability of claim 14.

Withdrawal of the rejection of claim 1 and the claims dependent therefrom is respectfully requested.

#### **Claim 7**

Independent claim 7 is directed in part an oral hygiene product comprising melatonin and an anti-oxidant “in an effective amount to prevent degradation of the melatonin.”

In contrast, the only mention of melatonin in the Cutler patent is in claim 17, as one of five antioxidants that may be included in the dental products described therein. *See claim 17 (“... antioxidant selected from the group consisting of ascorbic acid,  $\alpha$ -tocopherol,  $\beta$ -carotene, coenzyme Q<sub>10</sub>, and melatonin)(emphasis added).* Applicants submit that this disclosure does not teach a composition comprising melatonin and an additional anti-oxidant “in an effective amount to prevent degradation of the melatonin” as recited in claim 7.

The Cutler patent therefore cannot anticipate claim 7, as it does not teach or suggest each and every element of claim 7.

**Claim 8**

Independent claim 8 is directed in part an oral hygiene product comprising “a preservative selected from the group consisting of benzoic acid, salicylic acid, sorbic acid, and an essential oil.”

The Cutler patent does not mention “a preservative selected from the group consisting of benzoic acid, salicylic acid, sorbic acid, and an essential oil.”

The Cutler patent therefore cannot anticipate claim 8, as it does not teach each and every element of claim 8.

In response to the Examiner’s statement that “[e]ssential oils are disclosed in claim 1 of the Cutler patent, Applicants note that claim 1 of the Cutler patent recite that the claimed dental product is “... **free** of irritating flavors and essential oils ...” *See the Cutler patent, column 9, lines 41-43.* Applicants submit that because the claimed product of the Cutler patent is “free” of essential oils, it does not contain essential oils.

Withdrawal of the rejection is respectfully requested.

**Claim 13**

Independent claim 13 is directed in part an oral hygiene product “wherein an amount of the active in the oral hygiene product is 5% by weight.”

As stated above, the Cutler patent mandates that the products described therein “contain no less than 10 weight percent of xylitol.” *See column 5, lines 37-38.* The Cutler patent therefore does not teach an oral hygiene product “wherein an amount of the active in the oral hygiene product is 5% by weight” as recited in claim 13.

Withdrawal of the rejection is respectfully requested.

**D. Claim Rejections- 35 U.S.C. § 103**

**1. US 6,048,886 to Neigut**

Claims 1-8 and 13-14 were rejected under 37 U.S.C. § 103 (a) over U.S. Patent No. 6,048,886 to Neigut (“the Neigut patent”).

The rejection is respectfully traversed. Independent claims 1, 7, 8, and 13 are all directed in part to an oral hygiene product with an active consisting of melatonin, wherein the oral hygiene product is “in a form of a tooth paste, a mouthwash or an animal feed.”

In contrast, the Neigut patent is purportedly directed to compositions containing ubiquinone. *See e.g., Abstract*. The Neigut patent states that “[t]he chief requirements of [the invention described therein] ... is that ubiquinone (which can be present at a weight percentage ranging from 0.01 to 99%) is either combined with abrasive or is delivered transdermally.” *See column 6, lines 57-59*. The abrasives exemplified are “ground fruit pits, ground nut kernels, ground nut shells, grain hulls ..., saw dust, aluminum oxide, silica san, pumice, plastic and acrylic grit, plastic flour, and ground corn cobs.” *See column 5, lines 58-63*.

Applicants respectfully submit that active of the Neigut patent (i.e., ubiquinone) is excluded from the scope of the present claims by virtue of the “consisting of” language. Applicants further submit that the Neigut patent would not have suggested a product without ubiquinone, because ubiquinone must necessarily be present in a composition of the Neigut patent. *See e.g., column 6, lines 57-59*.

Applicants further submit that the Neigut patent does not suggest an oral hygiene product “in a form of a tooth paste, a mouthwash or an animal feed” as recited in the present claims. Applicants note that an abrasive of the Neigut patent are incompatible with an oral hygiene

product of the present claims and may produce ulcers upon application to oral mucous membrane.

With further regard to claims 6 and 8, Applicants submit that the Neigut patent does not teach or suggest a product comprising a specific preservative as recited in these claims.

With further regard to claim 7, Applicants submit that the Neigut patent does not teach or suggest an oral hygiene product comprising melatonin and an additional anti-oxidant “in an effective amount to prevent degradation of the melatonin.”

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

**2. Combination of US 5,900,230 to Cutler and US 6,048,886 to Neigut**

Claims 1-8 and 13-14 were rejected under 35 U.S.C. § 103 (a) over the Cutler patent in view of the Neigut patent, and vice versa.

The rejection is respectfully traversed. Independent claims 1, 7, 8, and 13 are all directed in part to an oral hygiene product with an active consisting of melatonin, wherein the oral hygiene product is “in a form of a tooth paste, a mouthwash or an animal feed.”

Applicants respectfully submit that the “consisting of” language in claims 1, 7, 8, and 13 excludes the presence of the actives of the Cutler patent (i.e., a mixture of (i) poloxamer and/or poloxamer and (ii) xylitol) and the Neigut patent (i.e., ubiquinone)).

Applicants therefore submit that the combination of the cited references, even if properly combinable (a position which is traversed), does not suggest an oral hygiene product as recited in the present claims (i.e., a product which excludes the mandatory actives of the cited references).

With further regard to claims 6 and 8, Applicants submit that the combination of the cited references, even if properly combinable (a position which is traversed), does not teach or suggest a product comprising a specific preservative as recited in these claims.

With further regard to claim 7, Applicants submit that the combination of the cited references, even if properly combinable (a position which is traversed), does not teach or suggest an oral hygiene product comprising melatonin and an additional anti-oxidant “in an effective amount to prevent degradation of the melatonin.”

Applicants respectfully note that one skilled in the art would not have combined the cited references in a manner suggested by the Examiner. The Neigut patent advocates inclusion of an irritant (i.e., abrasive) into the compositions described therein. *See e.g., column 5, lines 48-56 (“it has been found that the inclusion of an abrasive substance in the formulations [described therein] ... **surprisingly and significantly** enhances their effectiveness ...”) (emphasis added).* The Examples of the Neigut patent describe other irritants and antimicrobials (e.g., alcohol). *See e.g., columns 7-10.*

In contrast, the Culter patent is directed to a different utility and mandates that the dental product be “**free** of irritating flavors and essential oils ... [and] are ... **free** of harsh antimicrobials.” *See Id., lines 40-47.* The Cutler patent expressly teaches to “remove all irritants from the toothpaste,” and teaches that if the irritants are reintroduced the dental health deteriorates. *See column 6, lines 11-21.* Therefore, the Cutler patent would not have suggested to one skilled in the art to utilize the excipients (e.g., irritants or alcohol) of the Neigut patent.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

**3. US 6,200,550 in view of US 5,900,230 to Cutler and US 6,048,886 to Neigut**

Claims 1-8 and 13-14 were rejected under 35 U.S.C. § 103 (a) over US Patent No. 6,200,550 to Masterson et al. ("the Masterson patent") in view of the Cutler Patent and the Neigut patent.

The rejection is respectfully traversed. Independent claims 1, 7, 8, and 13 are all directed in part to an oral hygiene product with an active consisting of melatonin, wherein the oral hygiene product is "in a form of a tooth paste, a mouthwash or an animal feed."

Applicants submit that the Masterson patent is directed to an oral care composition comprising Coenzyme Q<sub>10</sub>. *See, e.g., Abstract*. Applicants respectfully submit that the "consisting of" language in claims 1, 7, 8, and 13 excludes the presence of the active of the Masterson.

Applicants therefore submit that the combination of the cited references, even if properly combinable (a position which is traversed), does not suggest an oral hygiene product as recited in the present claims (i.e., a product which excludes the mandatory actives of the cited references)

Applicants further submit that one skilled in the art would not have combined the cited references for the reasons set forth above.

In response, to the Examiner's statement that "Masterson discloses toothpastes comprising 0.2 to 2 percent by weight of melatonin (column 7, line 2)," Applicants respectfully note that the disclosed "0.2 to 2 percent" range is for tocopheryl acetate and  $\beta$ -carotene, not melatonin.

With further regard to claim 14, Applicants submit that the combination of the cited references does not teach an oral hygiene product "in the form of an animal feed." Applicants further submit that the term "in the form of an animal feed" is not merely "an intended use of the



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composition.” In fact, it defines the product of claim 1. Accordingly, this term should be taken into account in determining patentability of claim 14.

For the foregoing reasons, Applicants respectfully request withdrawal of the rejection.

### CONCLUSION

An early and favorable action of the merits is earnestly solicited. According to currently recommended Patent Office policy the Examiner is requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,

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